

BECKMAN

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Summary of Safety & Effectiveness IMAGE™ Immunochemistry System Microalbumin (MA) Reagent

1.0 Submitted By:

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2.0 Date Submitted:

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3.0 Device Name(s):

3.1 Proprietary Names

IMAGE™ Immunochemistry System Microalbumin (MA) Reagent

3.2 Classification Name

Albumin immunological test system (21 CFR § 866.5040)

4.0 Predicate Device(s):

IMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMAGE System Microalbumin (MA) Reagent	Beckman MA Microalbumin Reagent Kit	Beckman Instruments, Inc.	K895883

Beckman Instruments, Inc.

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5.0 **Description:**

The IMMAGE Immunochemistry System MA Reagent in conjunction with Beckman Urine Protein Calibrator, is intended for use in the quantitative determination of micro quantities of albumin in human urine samples on Beckman's IMMAGE™ Immunochemistry System.

6.0 **Intended Use:**

The IMMAGE Immunochemistry System Microalbumin (MA) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Urine Protein Calibrator, is intended for the quantitative determination of micro quantities of albumin in urine by rate nephelometry.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System MA Reagent	Analytic Range	Same as Beckman Microalbumin Reagent Kit
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System MA Reagent	Antigen excess testing solution	IMMAGE MA has antigen excess testing solution included in the reagent cartridge, while the Beckman Microalbumin Reagent Kit requires off-line preparation of the solution.
	Antibody concentration	IMMAGE MA has a higher antibody concentration than the Beckman Microalbumin Reagent Kit

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Beckman Reagent on the Array® 360 System to the IMAGE System Reagent.

Method Comparison Study Results IMAGE Microalbumin (MA) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMAGE MA Reagent	urine	0.957	-0.03	0.991	109	Beckman MA Reagent

Stability Study Results

Reagent	Product Claim
IMAGE MA	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	0.56	0.042	7.5	80
Level 2	2.25	0.107	4.7	80
Level 3	3.19	0.063	2.0	80
Total Imprecision				
Level 1	0.56	0.055	9.8	80
Level 2	2.25	0.121	5.4	80
Level 3	3.19	0.073	2.3	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.